STATEMENT OF MIKE SZYMANCZYK

CHAIRMAN AND CHIEF EXECUTIVE OFFICER

PHILIP MORRIS U.S.A.

on

FDA REGULATION OF TOBACCO PRODUCTS

Submitted to the Committee on Health, Education, Labor and Pensions
United States Senate

September 19, 2002

Written Statement of Mike Szymanczyk
Chairman and Chief Executive Officer
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I. Introduction

On behalf of the nearly 13,000 employees of Philip Morris U.S.A., I am very pleased to submit these remarks, and to express our strong support for passage by the 107th Congress of meaningful and effective regulation of tobacco products by the Food and Drug Administration. In addition, we offer our enthusiastic support of an equitable and reasonable plan to provide quota holders and active tobacco farmers with fair compensation, in connection with a plan to replace the current Federal tobacco program with a system that would limit the future production of tobacco leaf to counties where it is currently grown.

FDA regulation of tobacco products is an important Federal initiative that is certainly needed. Looking back, we accept responsibility for our role in the disputes, the misunderstandings, and the lack of resolve on this issue in the past. However, for more than two years we have urged passage of an effective and comprehensive FDA regulatory policy, and we are determined to be a constructive force for leadership in the effort that lies ahead to shape this policy.

When we say that we strongly support "effective" regulation by the FDA, we mean it. We're not playing word games or referring to a weak or watered-down plan. "Effective", to Philip Morris U.S.A, means a regulatory plan that is

designed and funded in a way that really means it can fully accomplish its stated objectives:

- Providing smokers with additional information about what's in their cigarettes and about the dangers of smoking now and on an ongoing basis, as new information becomes available;
- Assuring that – on an industry-wide basis – responsible tobacco marketing directed toward adults doesn't inadvertently encourage kids to start smoking;
- Aiding in the development of products that meaningfully reduce the harm caused by smoking; and
- Guiding the accurate communication of any potential risks and benefits of reduced risk or reduced exposure products that may be developed, which includes being sure to always communicate that there is no "safe" cigarette.

"Effective" to us does not mean regulations that are loophole-ridden or intentionally weak, punitively cumbersome for any party, or likely to generate unintended negative consequences...it means real reforms that get the stated and agreed upon job done.

I hope that today will mark the beginning of a new and much better chapter -- the most important and positive to date -- in the effort of society as a whole to come to a place where it feels certain that tobacco products, and the tobacco industry, are properly regulated given both the dangers of the products and the acknowledgement that adults should continue to be able to make informed decisions about smoking for themselves.

We thank this Committee for taking a leadership role on this important initiative, and look forward to working with you and your colleagues in the full Senate toward the passage of legislation that is designed to benefit adult consumers, eliminate an anachronistic quota system while compensating quota holders and paying growers, reduce the harm caused by tobacco consumption,

and establish clear rules for the tobacco industry that will apply to all industry participants and be enforced uniformly on all tobacco products sold in the United States.

We believe that additional regulation makes sense for a number of reasons. In spite of the rhetoric and controversy that continue to surround our industry and our company, we at Philip Morris U.S.A spend most of our time trying to improve our products so that they have the potential of reducing the harm caused by smoking, running our factories, working with our suppliers, making our payroll and paying our taxes. We are asking for new regulation because today there are simply not as many clear guidelines for the design and manufacture of, or communication to consumers about, our product as there ought to be. What rules there are increasingly arise at the state level, which will inevitably lead to conflicting standards that could confuse consumers, disrupt interstate commerce and significantly complicate orderly and uniform manufacturing and distribution processes.

FDA regulation would better align our business practices with society's expectations, and would further our goal of being a responsible, effective and respected manufacturer and marketer of tobacco products for adults who smoke. We believe Americans support meaningful, effective and reasonable new regulation of tobacco product manufacturing processes and consumer communications, especially those relating to potentially reduced risk products. They also support efforts to continue to build the momentum that has developed toward reducing the incidence of youth smoking. What they don't want is for the

new rules to go too far, and significantly intrude on adults' continued ability to smoke if they want to.

When Philip Morris U.S.A first announced its support for FDA regulation of cigarettes, some were surprised or skeptical because our company – along with other major manufacturers, retailers and advertising groups – had opposed the agency's assertion of jurisdiction over tobacco products under the medical device statute in 1996. That opposition was vindicated in 2000 when the Supreme Court agreed with our contention that, because cigarettes have no medical purpose and could never be deemed to be "safe and effective", the FDA would have had no choice under existing law other than to prohibit their sale entirely. Our opposition to the FDA's unilateral initiative was not an opposition to regulation *per se*, but rather opposition to *that specific* kind of regulation. We continue to believe that regulation of tobacco products as medical devices would be a mistake – not because nicotine is not a drug; it is, and we agree that cigarette smoking is addictive – but rather because tobacco regulation needs to be focused on how we can reduce the harm to society of a dangerous, agriculturally-based product that is nonetheless legal for adults to use, and the medical device rules simply are not based on that premise.

That is why we are very pleased that S. 2626, sponsored by Senators Kennedy, DeWine and others, regulates tobacco products under a new chapter of the Food, Drug & Cosmetic Act designed especially for such products. We're convinced that this is the right approach and, while we may not agree with every provision in this bill, we do think that this is a generally sound piece of legislation

that we hope to work with you on and, ultimately, see enacted into law. As we hope you will conclude from the rest of this Statement, there is far more common ground in our views than there are disagreements. Although on some issues there are important differences of opinion, they are truly differences in degree only. We believe that if the rancor and hostility of the past can be set aside, a new, national tobacco policy can be crafted that will effectively deal with tobacco issues without unintended consequences for the millions of consumers, employees, tobacco growers and retailers who will be dramatically affected by the results of your work.

II. Our Role in this Process

Some have advocated that tobacco companies and other industry participants should be excluded from discussions relating to tobacco policy. Philip Morris U.S.A. does not agree. No one group should attempt to dictate a solution to these complex issues. If this effort is to be successful and actually result in the passage of effective and comprehensive legislation, voices from across the political and economic spectrums need to be heard. Although we were not invited to testify before the Committee today, we hope to have an opportunity to make a meaningful contribution to your deliberations.

Many people, including some tobacco control advocates, have recognized that it is critical that our industry be given an opportunity to contribute its expertise, knowledge and point of view to the debate over the issues raised by this process. For example:

- A recent study sponsored by the American Council on Science and Health (August 2000) asserts that "[i]t is not enough to dismiss an argument or a

question on the ground that it is 'paid for by the tobacco industry'. Instead, all arguments, even those straight from the mouths of the cigarette makers, must be evaluated on their own merits. If the arguments are poor ones, they should be easily refuted."

- In 1998, Canada's Expert Committee on Cigarette Toxicity Reduction concluded "...a 'less harmful' tobacco product that is not acceptable to the consumer will not have a significant public health impact. Consequently, input from industry-based scientists is essential when product standards and product modification are being considered."
- A 1998 Food and Drug Law Institute conference (chaired by Drs. Henningfield and Slade, among others) stated that "[t]here is a considerable need for investment in research on both tobacco products and on treatment medications and modalities...The tobacco industry's cooperation in sharing its vast knowledge of tobacco and nicotine is crucial to this process."

We have some thoughts regarding this bill that we believe are worthy of serious consideration, as other stakeholders undoubtedly do, too. We'd like to help forge a consensus, so that the FDA can get started as quickly as possible on framing the new regulations.

Finally, we are aware of, and sensitive to, concerns that have been raised to the effect that tobacco manufacturers attempt to influence public policy issues "behind the scenes", or through undisclosed support of third parties. Our advocacy of meaningful FDA regulation cannot have been more public, and we've been very straightforward about the fact that we have been discussing this issue with many Members of Congress – on both sides of the aisle – as well as the Administration in the hopes of this effort succeeding. We want this Committee to know that all of our activities in support of this effort are being conducted in accordance with our Attribution Policy, which requires disclosure when we direct third parties to present data or views in order to influence policy issues of immediate interest to the company.

III. Our Support of Effective Tobacco Regulation, In the Context of S. 2626

Philip Morris U.S.A. has, for more than two years, been advocating many of the elements encompassed in S. 2626. We are not, however, under the illusion that Congress will simply convert our positions into legislative language and vote. The whole point of the legislative process is to reconcile the varying views of interested parties, which in this case includes tens of millions of Americans. We're not saying that it must be our way on all issues or we will oppose this legislation. Instead, we respectfully offer the following reactions and suggestions to the bill under consideration, in the hope of improving it and helping to ensure that it has a better chance of being enacted.

We start with the core issues that, in our opinion, are the most susceptible to unintended consequences if not crafted carefully, and are therefore most critical to ensure that the fundamental objectives of the legislation are not undermined. There are three core issues where the FDA should be broadly empowered, but sensibly directed, by Congress to reduce the harm caused by tobacco consumption, on a truly nationwide basis, in the context of preserving adults' ability to make their own decisions: reduced risk products, performance standards and national uniformity. Our perspectives regarding these areas are intended to help this Committee, and ultimately Congress, craft for the first time a truly effective, coherent national tobacco policy that can achieve the requisite consensus to be enacted into law.

We then turn to the other regulatory powers conferred by S. 2626, many of which – such as adulteration, misbranding, warning labels and good

manufacturing practices – make up the actual "nuts and bolts" of any comprehensive regulatory regime. Philip Morris U.S.A supports FDA involvement in *all* of these areas; the suggestions we offer below are intended to help create a new regime that will function as effectively as possible, based upon our operational experience and insights as the leading manufacturer in the industry that is to be regulated, and the years we have now accumulated working with the States to fully implement the terms and conditions of the Master Settlement Agreement.

III(A) – Core Issues for Achieving Meaningful Harm Reduction Nationwide, While Avoiding Unintended Consequences

Reduced-Risk and Reduced-Exposure Products

Philip Morris U.S.A. is committed to developing and marketing products that may be less harmful to smokers than today's conventional cigarettes. However, the government and the public health community should play an integral role in this process. Just as public health officials would object to reduced-risk claims that they have not had the opportunity to review and validate, consumers should view skeptically claims about new technologies that have not been sensibly regulated. We are particularly mindful of the critical need for manufacturers to work with the public health community to emphasize the fact that all smoking is dangerous, and that the best option from a health perspective is to quit or not to start in the first place.

For these reasons, we are convinced that the authority Congress grants to the FDA in this area is of critical importance. S. 2626 makes an excellent start in

this area, but in our opinion requires some important changes so as to better encourage the development and introduction of products that may truly reduce harm, and to better reflect the principles articulated by the recent report (*Clearing the Smoke)* of the Institute of Medicine on reducing the harm caused by tobacco, which was commissioned by the FDA itself. We hope that everyone can agree that the agency should not inadvertently be directed to actually *inhibit* the development of these products, and in the process to deny millions of today's consumers a genuine opportunity to reduce their chance of contracting tobacco-related disease.

In their report, the IOM committee made two important, fundamental recommendations: (i) determinations about what is, and what is not, a reduced-risk or a reduced-exposure product should be made by the government on a purely scientific basis and (ii) any claims made about such products should be strictly regulated to ensure that consumers are not misled:

> **Some public health officials oppose the adoption of harm reduction strategies because of concerns that promoting this approach will not, over the long term, prove to be beneficial to public health or to the individual tobacco users who might otherwise have quit. Whatever the merits of this position, marketplace forces already at work have put this issue on the policy agenda, and new products are being developed and offered as harm-reducing alternatives to conventional tobacco products...Manufacturers should be permitted to market tobacco-related products with exposure reduction or risk reduction claims only after [FDA] approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, compared with whatever benchmark product [FDA] requires to be stated in the labeling... [The] regulatory process should not discourage or impede scientifically grounded claims of reduced**

exposure, so long as steps are taken to ensure that consumers are not misled... [I]n the absence of sufficient scientific evidence to support a claim that a product may reduce the risk of disease, any claim of reduced exposure to tobacco toxicants should be accompanied by a statement that the health consequences of the change are unproven (or unknown)...The labeling, advertising and promotion of all tobacco-related products with exposure reduction or risk reduction claims must be carefully regulated under a 'not false or misleading' standard, with the burden for proof of the claim resting on the manufacturer.

Our suggestions for improving section 913 are all designed to have the legislation better reflect these principles, and to make sure that the FDA does not misinterpret its mission as impeding, rather than encouraging, overall harm reduction. They include:

- Introducing the concept of "reduced exposure" products, in addition to the "reduced risk" authority already in the draft;
- While retaining the FDA's authority as the arbiter of what is and is not a genuinely reduced-risk or reduced-exposure product as a matter of science, removing the suggestion of the current draft that the agency might decline to certify such a genuine product based on the notion that its scientific conclusions should be suppressed, because adult consumers cannot be trusted to make good decisions on the basis of those conclusions; and
- Clarifying the FDA's authority over the marketing and labeling of these products to embody a 'not false or misleading' standard.

We also note, with regard to the second bullet, that both the Supreme Court and several Courts of Appeals have strongly indicated that the kind of suppression of truthful information that appears to be contemplated by S. 2626 cannot withstand scrutiny under the First Amendment. A white paper discussing these cases in greater detail is attached to this Statement.

Performance Standards

We support a grant of authority, such as that contained in section 907, to the FDA to reduce harm by imposing mandatory design changes on tobacco products, even including changes that consumers might not like. Our main concern with this section, as currently drafted, is that by its terms it would permit the agency to do what nobody should want: to impose changes that are so radical that tobacco products are effectively banned, or consumers are driven away from the legitimate market and towards illicit, completely unregulated products.

We believe that the agency should have the authority to ensure that ingredients added to tobacco products do not increase their inherent health risk or addictiveness; because added ingredients are under the manufacturers' control, this authority should, in our view, *include the power to prohibit any added ingredient shown to increase health risks even if the ban would impact the product's taste.* Apart from added ingredients, we also support authority for the FDA to impose changes to the other design or inherent characteristics of a tobacco product – including the inherent properties of tobacco leaf itself – that it believes will protect public health, so long as the changes are technically feasible and would *not* negatively impact adult consumers' enjoyment of the product in a significant way. There is no public consensus for FDA actions that *force* radical changes on the design or inherent characteristics of today's tobacco products that adult smokers may not be prepared to accept. We believe that instead, the FDA should use its enormous persuasive powers and regulatory tools to

encourage consumers to quit, or to switch to products whose design and composition the agency favors from a public health perspective.

Added Ingredients

The current draft of S. 2626 contemplates the use of "performance standard" authority by the FDA to regulate ingredients added to tobacco products based on its belief of what would be appropriate to protect public health. We believe that this is a legitimate role for the agency to the extent it is used to ensure that ingredients do not change the overall risk profile of the product, including by increasing its addictiveness. Tobacco products are inherently dangerous, but the government should have authority to make sure that nothing is added by manufacturers to make them even more so. Philip Morris U.S.A. stands ready to submit *all* of its added ingredients to rigorous FDA review and testing, and to work with the agency as it makes its own assessment of any added risks they may present.

An approach that focuses on increased risk from ingredients has been explicitly adopted by the recent IOM Report:

> **...[FDA] should...have the authority to remove from the market ingredients...that do not meet [a] test of no increased risk..."**

To be clear, we think that FDA authority to test and, if necessary, prohibit the use of specific ingredients it finds to increase the inherent risks of smoking should apply to ingredients *currently in use* as well as to new ones. There should be no "grandfathering."

However, the authority conferred by section 907 over added ingredients extends beyond the concept of "increased risk". Its unlimited scope would permit the FDA, for example, to prohibit specific ingredients solely because they improve the taste of a tobacco product, on the theory that, by trying to make the products taste bad, consumption will drop and public health will be benefited. The way the provision is currently drafted, the FDA could even order that bad-tasting ingredients be added to cigarettes, so as to decrease their palatability. These powers are, we respectfully submit, simply incompatible with the principle that tobacco products are legitimate and that adults should continue to be permitted to consume them if they wish. To quote from the preamble to the FDA's own proposed tobacco rule:

> **Black market and smuggling would develop to supply smokers with these products...[which] would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.**

If regulation of cigarettes is to be based purely on eliminating their known inherent dangers, we readily agree that it would be best if nobody smoked at all. But Americans want to see a new regulatory regime that incorporates other values as well – tolerance, adults' continued ability to make their own decisions about issues that affect their health, law enforcement considerations, and the degree to which government should intrude generally into the realm of personal issues.[1] If Congress is to reflect this consensus and balance these competing

[1] Indeed, the reason that the Supreme Court rejected FDA's initial "medical device" tobacco rule is that it determined that, under that approach, the agency would have *been required* to ban tobacco products, and

concerns, it will need to tailor the FDA's authority so it is focused on encouraging harm reduction, rather than trying to force Americans to adopt tobacco-free lifestyles.

Smoke Constituents and Other Mandatory Design Changes

For the same reasons, we do not believe that the FDA should have unlimited power to require the reduction or elimination of smoke constituents (the inherent properties produced by tobacco when burned), or to order other mandatory design changes in tobacco products that adults find unacceptable. For example, under the current version of section 907, the agency could force radical reductions in tar and nicotine yields, or require that manufacturers utilize filters that would eliminate the products' taste. Strategies such as these may well be valid in the effort to reduce harm, but we respectfully suggest that they are best dealt with under S. 2626's section on reduced-risk products (section 913), discussed above. Using the authority conferred under that section, the FDA will have enormous ability to use its credibility with the American people to persuade them to switch to any alternative product designs of its choosing. It should not be given the power to impose mandatory changes that impact taste in ways that adult consumers might not accept.

Authority to Ban Tobacco Products

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that such a ban could not be squared with the overall national tobacco policy already put in place by Congress.

Section 907 even goes so far as to expressly permit the FDA to ban the sale of cigarettes or other tobacco products to adults if it concludes that such action would be "appropriate to protect the public health." This power should not reside in any regulatory agency. It should be retained by the Congress and be executed only if and when it represents the will of the people. Since the American public doesn't support Prohibition of tobacco, this portion of section 907 is simply inappropriate.

National Uniformity

We support the principle embodied in section 918 that State and local authority should be preserved for such issues as taxation and access restrictions designed to prevent minors from purchasing tobacco products. We also support the portions of that section providing that on key issues relating to the product, such as performance standards and good manufacturing practices, there should be uniform, nationwide standards that apply equally to all tobacco products sold in the United States.

However, there are some clauses in section 918 that render the principle of nationally uniform product standards meaningless and potentially lead to unintended consequences, for example, by exempting State and local laws that are "more stringent" than Federal standards, or permitting the FDA to waive the requirement of national uniformity on a case-by-case basis. We hope to work with this Committee to convey the enormous logistical and financial burdens that a patchwork system of conflicting State product requirements would impose on

both manufacturers and consumers, without any clear benefit to public health. Consider, for example, the potential for consumer confusion if the Marlboro for sale in New York has different product characteristics than, or a different taste from, the Marlboro available in Pennsylvania.

If the FDA uses its enormous expertise to regulate a particular ingredient, or to devise a new test method for measuring smoke constituents, or to develop a standard for reduced-risk products, why should any particular State want – or be authorized – to create the confusion that would arise from the imposition of conflicting requirements? Cigarettes in this country are not, for the most part, manufactured locally or designed to suit local preferences; in Philip Morris U.S.A.'s case, we have two major facilities that manufacture our brands, in the same way, for the entire country. Legislation for FDA authority should respect the integrity of the standards that the agency promulgates, and preserve national product uniformity by having true preemption provisions for product issues.

On a different but related issue, we strongly oppose S. 2626's proposed deletion of existing statutory provisions that preserve the uniformity and integrity of Congress' nationwide health warning labels for cigarettes. In the absence of these provisions, manufacturers might be required to publish a multiplicity of conflicting warnings from State to State. This would again lead to results that are not apparent from the face of the legislation: the undermining of the federal government's ability to ensure that consistent, appropriate warning information is communicated clearly to the public and consumers. Such a result also could be an unnecessary boon to trial attorneys, who might encourage juries to second-

guess Congress' judgment as to the adequacy of the health warnings; even though, as noted below, the FDA will have the authority to revise their content if it chooses. Current law's preemption relating to health warnings has not resulted in "immunity" for cigarette manufacturers, which still face causes of action under state law that the Supreme Court ruled have not been preempted.

III(B) – The "Nuts and Bolts" of FDA Regulation; Our Support of a Comprehensive Regime and Some Technical Suggestions for Improving the Bill

Adulteration

- *Our Support of the Issue.* We support the provisions of section 902 of S. 2626 giving the FDA authority to remove adulterated tobacco products from the market. We strongly believe that all products should be required to be manufactured under conditions that are free from contaminants.

- *Our Suggestion.* Our only suggestion here is technical, but also illustrative of the pitfalls of simply applying medical device provisions in the tobacco product context. The bill provides that a tobacco product is adulterated if it consists of any substance that renders it "injurious to health". Since all cigarettes available today cause lung cancer, heart disease, emphysema and other serious diseases in smokers, they would all be "adulterated" under the current draft, and thus subject to removal from the market. This section can be fixed by specifying that a tobacco product is

adulterated if it contains substances that render it *more* injurious to health than do today's conventional products.

Misbranding

- *Our Support of the Issue.* We generally support the misbranding provisions contained in section 903, as we strongly believe that the FDA should be empowered to ensure that the labeling of tobacco products is not false or misleading. Indeed, we are pleased that these provisions have been strengthened to include labeling of domestic leaf content, which will – because of consumer demand for the high quality of U.S.-grown tobacco -- enhance the competitiveness of our nation's tobacco farmers.

- *Our Suggestion.* In addition, we think that S. 2626's provisions in this area could be strengthened by adding (i) the ingredients-disclosure provisions from H.R.1043 (requiring by-brand disclosure of all ingredients to the same degree as food products) and (ii) the *mandatory* regulation within 12 months of terms such as "light" and "low tar" required by S. 2764 to ensure that these terms are used consistently, and are neither false nor misleading.

Submission of Health Information to the FDA; Registration

- *Our Support of the Issue.* We fully support section 905, requiring the submission to the FDA of detailed information about each tobacco product brand on an annual basis. We believe that, on all matters implicating smoking and health, the FDA should know whatever the manufacturers know about the relevant scientific issues. In addition, we fully support the registration and inspection provisions of this section; in fact, we'd like to see them strengthened to make it clear that the FDA will have the same obligation to inspect foreign cigarette factories that supply the U.S. market as it does domestic ones, as required by S. 2764.

Authority Over Advertising of, and Access to, Tobacco Products

- *Our Support of the Issue.* Philip Morris U.S.A. strongly believes that cigarettes should only be marketed to adult smokers, and supports regulations that build upon its voluntary actions to reduce kids' exposure to its brand advertising. Moreover, we strongly support both legal requirements and programs designed to prevent minors from obtaining access to cigarettes. Thus, while we do not favor the breadth of authority over advertising of, and access to, tobacco products that section 906(d) of S. 2626 would confer upon the FDA, we are supportive of empowering the agency to administer, oversee and enforce a comprehensive Federal regime that includes both advertising and access restrictions.

Advertising Restrictions

- *Our Suggestions.* Although we are pleased that this provision now explicitly recognizes the fact that the FDA's rulemaking authority in this area is subject to First Amendment considerations, in our view it still goes too far by purporting to permit the agency to create rules about marketing that have nothing whatsoever to do with combating youth tobacco consumption. As an alternative to the advertising authority in section 906(d), we respectfully suggest that this Committee consider substituting specific new rules for marketing and access that, for example, will apply the restrictions of the Attorneys General Settlement Agreements with cigarette manufacturers to all industry participants, and restore to the FDA the authority to enforce a national minimum age law and ensure that all tobacco products are sold in transactions where age can be verified and all applicable taxes can be collected. If additional rulemaking authority for the FDA is considered necessary, such authority should at least be drafted so as to focus on reducing minors' exposure to tobacco advertising, while continuing to permit responsible marketing to adult consumers.

  We recognize that cigarette advertising is a polarizing topic, which is why Philip Morris U.S.A. has taken voluntary steps – over and above the terms of the settlements – to reduce the profile of its own cigarette advertising. (These steps include suspending tobacco

brand advertising in over 50 magazines that meet criteria for youth readership proposed by the FDA itself, and removing our advertising from the back covers of *all* magazines.) Rather than using this statement to debate the merits of the degree to which marketing should be restricted from a public health standpoint, it's enough for today to simply point out that attempting to give the FDA authority to restrict marketing to adult smokers will face substantial Constitutional hurdles. As a majority of Supreme Court justices recently said in the *Reilly* case:

> **The State's interest in preventing underage tobacco use is substantial, and even compelling, but it is no less true that the sale and use of tobacco products by adults is a legal activity. We must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products...As the State protects children from tobacco advertisements, tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication.**

Even the dissenting Justices did not quarrel with this essential truth, stating that they "share the majority's concern as to whether the 1,000-foot rule unduly restricts the ability of cigarette manufacturers to convey lawful information to adult consumers". Power without meaningful limitation in this area simply will not work in this country.

Instead, there is much to be gained by Congressional codification of marketing restrictions based on those contained in the settlements (including those which go even further than the FDA's

1996 proposed rule), which currently apply to some, but not all, manufacturers, and do not apply at all to wholesalers, distributors and retailers. These include:

- Prohibition on youth targeting
- Minimum package size
- Ban on free sampling where minors are present
- Ban on cartoon characters in advertising
- Ban on billboards and elimination of many forms of other outdoor advertising
- Restrictions on the size of outward-facing advertisements at retail
- Strict limitations on tobacco brand sponsorships
- Ban on tobacco brand merchandise
- Ban on gifts to minors based on tobacco purchases

In addition, your Committee may wish to consider codifying restrictions in other areas that were not specifically covered by the settlements, such as magazine advertising. But we urge you to narrowly tailor any new rules you create so that they are directed at protecting kids, rather than suppressing information about tobacco products for adults. We believe that only restrictions that are drafted with these principles in mind will ultimately survive judicial scrutiny.

Access Restrictions

- *Our Suggestions.* Providing unlimited authority to deny adults' access to tobacco products would be, we believe, out of step with the preferences of a majority of Americans. They certainly don't want distribution of tobacco products limited to State-Run Tobacco Outlets, as some in the tobacco control community have proposed. Yet section 906(d), as currently drafted, could be interpreted to permit the FDA to do this if the agency concluded that such action would be justified in the name of public health. Instead, we favor the creation and enforcement of additional rules designed to ensure that *minors* are denied access to tobacco products.

  Philip Morris U.S.A. has made substantial investments in programs that restrict access for minors, including incentives for retailers of our product to utilize non-self service and off-counter displays, and support of the Coalition for Responsible Tobacco Retailing's *We Card* program. We'd be happy to provide this Committee with more details about what we've learned from these efforts, and urge close consultation with the retail community and others who are affected by this issue. In our view, Congress should enact new rules restricting self-service displays, mail-order and Internet sales, vending machines, and other areas that make sense in terms of youth access control, but do not unreasonably prevent adults from conveniently purchasing tobacco products.

Good Manufacturing Practices

- *Our Support of the Issue.* For the same reasons that we endorse FDA authority to ensure that cigarettes are not adulterated, we support section 906(e) of S. 2626, which directs the FDA to create and require "good manufacturing practices" for tobacco products.

- *Our Suggestion.* We do, however, respectfully suggest that the legislation specify that the regulations that the FDA writes should be reasonable and appropriate for tobacco products, which are agriculturally-based and are not, for example, made under the same standards of sterility that are applied to pacemakers and syringes. Given the history on this issue, and a prior willingness to apply "medical device" manufacturing standards to cigarettes, we believe that it's important to clarify the statutory authority in this way.

Pre-Market Approval

- *Our Support of the Issue.* We support what appears to be the intent of S. 2626's pre-market approval provisions (set forth in section 910), which state that extensive pre-approval of new products is not necessary if they are "substantially equivalent" to products on the market at the time of introduction into commerce. This approach would track well with the recommendation of the recent IOM report on this subject:

In the absence of any claims of reduced exposure or reduced risk, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory agency after informing the agency of the composition of the product and upon certifying that the product could not reasonably be expected to increase the risk of cancer, heart disease, pulmonary disease, adverse reproductive effects, or other adverse health effects as compared to similar conventional tobacco products...Because the main regulatory purpose of a requirement for no increased risk is to help establish the baseline for future comparisons and to stimulate development and use of protocols for tobacco product risk assessment, pre-market notification is sufficient.

- *Our Suggestions.* Our suggestions regarding section 910 are technical in nature, and are all aimed at improving the drafting and clearing up of ambiguities so that this provision is fully consistent with the IOM recommendation. They also attempt to ensure that these provisions will not be misconstrued by the FDA so as to impede the development of potentially reduced-risk products, or to require the agency to misdirect its resources and unreasonably interfere with manufacturers' commercial operations, by conducting lengthy examinations of products that have no potential to reduce the harm caused by tobacco consumption. For example, we would like to work with the Committee to:

- Clarify that the definition of "substantially equivalent" is consistent with IOM's concept of "no increased risk" as compared to conventional products;
- Require that manufactures submit prior certifications that proposed new products do not present any increased risk, empower the FDA to disagree with that assessment at any time (even after the product is introduced into commerce) and to take appropriate

action, and make it clear that, in the absence of FDA action after a reasonable pre-certification period, product launches may proceed; and

- Explicitly state that products under review pursuant to the reduced risk provisions of section 913 would not also be subjected to section 910 pre-market approval.

We do not advocate – and S. 2626 would not provide – that pre-market approval provisions "grandfather" today's tobacco products from further regulation. In whatever form they eventually take, performance standards under section 907 would apply to *all* tobacco products (whether on the market today or introduced in the future), and the certification and marketing of potentially reduced risk products would be guided by the FDA under section 913.

Tobacco Products Scientific Advisory Committee

- *Our Support of the Issue.* We think the creation of this Committee is an excellent idea, and hope that, once constituted, it will be able to make important and far-reaching contributions to the scientific discussions relating to smoking, including issues relating to harm reduction for consumers.

Exports

- *Our Support of the Issue.* We fully support efforts by Congress to ensure that every tobacco product exported from the United States complies with the regulatory requirements of the country to which it is being shipped. Moreover, our sister company Philip Morris

International, as described in more detail in section IV(B), agrees with those in the public health community that want to press for regulation of tobacco products everywhere in the world, with broadly agreed standards on the most important issues relating to their design and manufacture.

- *Our Suggestions.* Tucked away in S. 2626's technical amendments to the FDA statute (section 103 of the bill) is a provision of large substantive importance for American tobacco growers and workers – a clause that would place exports of tobacco products from the U.S. at a competitive disadvantage with other brands marketed in the destination country by making American products (but not others sold there) comply with FDA-mandated product standards. It's hard to see how this attempt to dictate tobacco policy to foreign countries would protect public health; if, for example, the FDA imposes a tar ceiling in the U.S. of 12 mg per cigarette by the current standard method, but the destination country continues to permit the sale of cigarettes with higher tar yields, smokers in that country who prefer such products will simply switch to brands not manufactured here. Rather, the result of this provision, which we suggest is ill-considered, would be to force export manufacturing operations out of this country, with an accompanying loss of jobs and other economic contributions.

We urge this Committee to substitute a rule for exports that would require them to be clearly labeled as such (to ensure that non-conforming products are not sold here), and to comply with the regulations applicable in the destination country. Those regulations, at least, apply equally to all brands in the foreign market.

Health Warning Labels; Disclosure of Smoke Constituents

- *Our Support of New Warning Labels.* Philip Morris U.S.A.'s policy is to defer to governmental authorities as to the content of cigarette health warnings; we therefore fully support the bill's provisions starting at section 201 that require new texts, and empower the agency to create additional warnings as the science and new information evolves. Similarly, we accept the new formatting and size requirements that will increase the size of the health warnings to 25% of cigarette packages and 20% of advertisements.

- *Our Suggestion.* Our only major concern in this area is that the bill make clear that these size limitations cannot be modified by the FDA without further action by Congress.

- *Our Support of Disclosure of Smoke Constituents.* We support section 205, giving the FDA the authority to test cigarette brands for their yields of tar, nicotine and other smoke constituents, and to

disclose information about these yields to consumers if the agency determines that doing so would benefit the public health.

IV. Additional Issues

We now briefly turn to two important issues that are relevant to important stakeholders, but are not directly addressed by S. 2626: a tobacco grower and quota-holder buyout, and Philip Morris International's support of meaningful regulation of tobacco products in every market in the world where it does business.

IV(A) -- Grower Buyout

S. 2626 does not have any provisions that would achieve an objective that is of great interest to many American tobacco growers – a program to enhance the long-term economic viability of U.S. tobacco production by removing the non-value-added cost of the Federal quota and price support program that burdens the current system. It's clear that the enthusiastic support of our nation's tobacco farmers is an important component of assuring the ultimate passage of legislation containing FDA regulation. We respectfully recommend that this Committee consult with their colleagues from tobacco-growing States and develop provisions, such as those contained in S. 2764, that link FDA regulation to the termination of the quota and price support provisions of the Federal tobacco program, finance both the quota buyout and the new regulatory system by means of a manufacturers' user fee, and define the nature of the marketplace for tobacco leaf in the absence of the Federal program.

IV(B) -- International Tobacco Regulation

Although Philip Morris U.S.A. does not conduct business outside the United States and its territories, our sister company Philip Morris International does, and both companies are acutely aware of the need to make progress on tobacco regulation in other countries that parallels the strides that the FDA initiative would make in the United States. We want the Committee to be aware that we support meaningful, reasonable regulation of tobacco products everywhere, and have manifested that support, for example, by supporting efforts initiated by the World Health Organization to sponsor a global treaty on tobacco control. Our detailed positions in this regard are available in numerous position papers and regulatory submissions (including one submitted last March to the Department of Health and Human Services at their request), all of which are available at www.pmfctc.com.

V. Conclusion

We believe that this body has the opportunity to forge a new national tobacco policy that will impose substantial new regulations on tobacco products, while continuing to permit adults who wish to use them to do so legally. The bill you are considering today could make a substantial contribution to making progress toward that goal. We hope this statement provides you with helpful input, and makes it clear that our company is truly supportive of a comprehensive and effective new regulatory regime that includes every area addressed by S. 2626, and in practice will actually result in what we think everyone should be able

to agree upon as a primary objective: reduced harm from tobacco consumption for both current and future generations.

In conclusion, we know that the issues we believe comprise both major parts of final FDA legislation are complex and controversial, but we pledge to work with anyone and everyone who wishes to join in this challenge, and commend this Committee for this progress as a critical first step.

Attachment 1

THE DEBATE OVER "REDUCED-RISK" AND "REDUCED-EXPOSURE" TOBACCO PRODUCTS: *Full Disclosure vs. Government Suppression of Truthful and Non-Misleading Information*

Competing proposals to give the FDA regulatory authority over tobacco products take different approaches to so-called "reduced-risk" or "reduced-exposure" products. These are products that have the potential to reduce the harm caused by today's conventional tobacco products by, for example, lowering smokers' risk of contracting tobacco-related disease, or their exposure to toxic substances in the smoke. The approach most consistent with sound public policy and First Amendment protections is that which provides consumers with more information about these products, rather than less or none at all. The FDA would be the one to decide both whether a product does indeed present reduced risks or reduced exposures, and what marketing claims about the product would be both truthful and not misleading. But once this determination is made, neither the FDA nor any other government body could suppress *truthful and non-misleading information about the product.*

Executive Summary

The debate over how to regulate "reduced-risk" and "reduced exposure" tobacco products has created a controversy within the public health community to some degree. On one side are those who share the view that the government should simply evaluate reduced-risk claims based on their scientific merits and deal with any public health concerns by providing for ***full disclosure to consumers*** and through other public health measures. On the other side are those who fear that these products, even with FDA or other governmental regulation, would have a net adverse public health impact by encouraging more people to start smoking in the first place and/or discouraging people from quitting, under the misguided view that smoking is now "safe." Therefore, this contingent supports giving the ***government authority to suppress*** reduced-risk claims about tobacco products.

The latter view flies in the face of the First Amendment and sound public policy. The Supreme Court has made it clear that suppression of information is not a useful or suitably tailored restriction on commercial speech.

In the instant case, the notion that benefits would result from the suppression of reduced-harm information is premised on the speculation that adults might use truthful and non-misleading information in a manner that is disfavored by the government. However, the Constitution does not recognize such an assumption as legitimate.

Moreover, suppressing information on reduced-risk tobacco products would not necessarily advance the government's interest in protecting public health. In order to

provide this speculative benefit to certain individuals, the government would have to impose clear harms on others -- specifically, those people who will use tobacco products regardless and who, because of the suppression of information, would be denied the ability to select products with demonstrated reduced-risk potential. Thus, a significant part of the population may be denied crucial information in order to "protect" a speculative segment of the population.

In addition, the government has available to it more narrowly tailored means of advancing its public health interests. For example, it could:

- ensure that consumers are given all necessary information to ensure that they are not misled regarding the health risks that remain with reduced-risk products or that quitting or not starting is still the most risk-free approach;
- stress other public health programs to encourage smoking cessation and prevention; and
- require that manufacturers conduct postmarketing studies to determine *actual* short-term and long-term consequences of using the product and to permit continuing review of the claims' accuracy.

In short, to quote the Supreme Court, ***"the preferred remedy is more disclosure, rather than less,"*** Bates v. State Bar of Arizona, 433 U.S. 350, 375 (1977) (emphasis added), and "[i]f the First Amendment means anything, it means that ***regulating speech must be a last -- not first -- resort***." Thompson v. Western States Medical Center, 122 S.Ct. 1497, 1507 (2002) (emphasis added). Indeed, "if the [g]overnment [can] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the [g]overnment ***must*** do so." Id. at 1506 (emphasis added). Accordingly, legislation should task the FDA with reviewing reduced-risk and reduced-exposure claims based on their scientific merits. The FDA also should have ample authority to ensure that consumers are provided with full disclosure regarding such products. Other public health tools should supplement these efforts by continuing to encourage smoking cessation and prevention. This approach is consistent with the approach outlined by the Institute of Medicine: "The regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, as long as steps are taken to ensure that consumers are not misled . . . ." Institute of Medicine, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (2001), at 218.

I. BACKGROUND

Last year, a report commissioned by the Food and Drug Administration ("FDA") on reduced-risk tobacco products was issued by the Committee to Assess the Science Base for Tobacco Harm Reduction (the "Committee") of the Institute of Medicine ("IOM"). In the report, the Committee acknowledged that there were varying views with respect to reduced-risk tobacco products within the public health community:

> "Despite overwhelming evidence and widespread recognition that tobacco use poses a serious risk to health, some tobacco users cannot or will not quit. For those addicted tobacco users who do not quit, reducing the health risks of tobacco products themselves may be a sensible response. This is why many public health leaders believe that what has come to be called 'harm reduction' must be included as a subsidiary component of a comprehensive public health policy towards tobacco.
>
> "Some public health officials oppose the adoption of harm reduction strategies because of concerns that promoting this approach will not, over the long term, prove to be beneficial to public health or to the individual tobacco users who might otherwise have quit. Whatever the merits of this position, marketplace forces already at work have put this issue on the policy agenda, and new products are being developed and offered as harm-reducing alternatives to conventional tobacco products."

Institute of Medicine, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (2001) ("IOM Report"), at 201-202 (internal citations omitted). The Committee sought to avoid taking sides in this debate, stating that "[t]he Committee's task is not to recommend whether or not tobacco harm reduction should be pursued." Id. at 202.

Nevertheless, the Committee made clear that it recommends a regulatory approach based on sound science and full consumer disclosure. Prior to detailing its

principles for the regulation of reduced-risk and reduced exposure products (sometimes referred to as "potential reduced exposure products", or "PREPs"), the Committee stated:

> "The committee did come to conclude that regulation of PREPs is necessary and feasible . . . *[R]egulation is needed to ensure that the product labeling and advertising do not mislead consumers and accurately describe the products' risks, including the uncertainties that can only be resolved after long-term use.* Consumers should not use these new products on the basis of explicit or implicit claims that these products carry less risk than traditional tobacco products unless such claims are true. ."

Id., at 203 (emphasis added).

Notwithstanding IOM's recommendations, however, S. 2626 appears to grant FDA authority to suppress truthful, non-misleading information about reduced-risk tobacco products even if the FDA has verified that these products, as a matter of science, may present reduced risks to consumers. The applicable provisions of this bill appear to respond to those segments of the public health community that have called for FDA discretion to suppress such claims. See Campaign for Tobacco-Free Kids, Critical Elements of FDA Authority Over Tobacco, Feb. 18, 2000 (stating that "FDA should have the authority to *prohibit* . . . health claims . . .") (emphasis added).

More specifically, S. 2626 would permit manufacturers to make reduced-risk health claims only if the FDA finds that "the product will significantly reduce harm to individuals caused by a tobacco product *and is otherwise appropriate* to protect public health." § 913 (emphasis added). Because S. 2626 provides this two-pronged standard -- a "scientific merits prong" and an "appropriateness" prong -- it apparently would give the FDA authority to withhold a reduced-risk designation, even if the FDA agrees as a matter of science that the product "will significantly reduce harm to individuals."

The "appropriateness" prong of this standard appears to be intended to address the concerns that have been raised about the potential impact of reduced-risk tobacco products on rates of smoking cessation and initiation. In this respect, S. 2626 provides the following four factors for the Secretary to consider in determining whether a product which significantly reduces harm is "appropriate to protect public health": (1) the risks and benefits to the population as a whole; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; (3) the increased or decreased likelihood that those who do not use tobacco products will start to use such products; and (4) the risks and benefits to consumers from the use of a reduced-risk tobacco product. Id.

Thus, under S. 2626, it appears that even if a product has been demonstrated to the FDA to genuinely present reduced health risks, the agency could prevent the product from being marketed with truthful and non-misleading reduced-risk information, resulting in the suppression of the reduced-risk information.

II. THE FIRST AMENDMENT PRECLUDES THIS KIND OF SUPPRESSION OF INFORMATION

This approach to the regulation of reduced-risk tobacco products would violate the First Amendment and sound public policy. First, the suppression of information would not materially and directly advance the government's legitimate interests in encouraging tobacco cessation and prevention. Instead, the suppression of information would harm a clearly identifiable group of individuals. Second, the government has far more tailored means at its disposal to address any impact of reduced-risk products on the rates of smoking cessation and initiation. Such alternatives include the mandatory use of

public health disclaimers to ensure that reduced-risk tobacco products are not perceived as safe, and the pursuit of other public health programs to encourage tobacco cessation and prevention.

The Supreme Court has repeatedly held that once a product is legally sold in the United States, the government may not deny adults truthful and non-misleading information about the product. Rather, the government must adopt more tailored restrictions to achieve its legitimate purposes. As the Supreme Court stated in its seminal commercial speech case:

> "There is, of course, an alternative to [a] highly paternalistic approach [to regulating commercial speech]. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us."

Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

"[B]ans against truthful, nonmisleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." Thompson v. Western States Medical Center, 122 S.Ct. 1497, 1508 (2002), citing 44 Liquormart v. Rhode Island, 517 U.S. 484, 503 (1996) (plurality opinion).

Last year, in Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), the Supreme Court struck down certain restrictions on the advertising of tobacco products because

those restrictions were not sufficiently tailored to fit the government's clearly legitimate objective of protecting children. This holding reaffirmed that the Court will carefully scrutinize commercial speech restrictions, including in the case of tobacco products, to determine if less restrictive means are available to achieve the government's purpose. The Reilly Court made clear that commercial speech restrictions continue to be subject to the following four-part inquiry developed by the Supreme Court in the Central Hudson case:

> "For commercial speech to come within [the First Amendment], it at least must concern a lawful activity and not be misleading. Next, we ask whether the asserted government interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the government interest asserted, and whether it is not more extensive than is necessary to serve that interest."

447 U.S. 557, 566 (1980). "We have said that the last two steps of the Central Hudson analysis basically involve a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." Rubin v. Coors Brewing Co., 514 U.S. 476, 486 (1995).

Simply put, the suppression of information about reduced-risk tobacco products does not fit the government's interest in encouraging tobacco cessation and prevention.

A. The Suppression of Reduced-Risk Information Would Elevate Presumed Benefits for Some Over Real Harms for Others

The premise behind providing the FDA with authority to suppress truthful and non-misleading reduced-risk information appears to be that the costs associated with the possible changes in the rates of cessation and initiation might outweigh the benefits that the reduction in risk would present. To tilt the balance in this fashion, however, one

would have to value the presumed benefits that may be provided to some over the real costs that would be imposed on others. Such conjecture, however, cannot justify the suppression of truthful and non-misleading commercial speech under the First Amendment. "Such speculation certainly does not suffice when the [government] takes aim at accurate commercial information for paternalistic ends." 44 Liquormart, 517 U.S. at 507.

Moreover, as detailed below, an abstract discussion about costs and benefits fails to illuminate the serious consequences of any decision to suppress information with respect to reduced-risk or reduced-exposure tobacco products.

1. The Paternalistic and Speculative Benefits Provided by the Suppression of Information Are Insufficient to Pass Constitutional Muster

The suppression of reduced-risk or reduced-exposure information presumably would be intended to benefit that segment of the population that would quit or never initiate smoking if information about these products is not available, but who would choose to switch to or begin using reduced-risk or reduced-exposure tobacco products if they were made aware of these products. Viewed from a "paternalistic" perspective, this segment of the population would be benefited by the suppression of information. Attempting to justify the suppression of reduced-risk information on this basis, however, is at odds with the Constitution, because paternalism is not a legitimate governmental interest, and because the realization of this paternalistic benefit would be impermissibly speculative.

The government "does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes . . ." 44 Liquormart, 517 U.S. at

510. Indeed, the Supreme Court has "rejected the notion that the [g]overnment has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." Western States, 122 S.Ct. at 1507. "[T]he argument [for suppression] assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public . . . . [W]e view as dubious any justification that is based on the benefits of public ignorance." Bates v. State Bar of Arizona, 433 U.S. 350, 374-375 (1977). "To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection . . . is practically an engraved invitation to have the restriction struck." Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 70 (D.D.C. 1998) (judgment vacated on other grounds). "[T]he government may not restrict speech because it fears, however justifiably, that the speech will persuade those who hear it to do something of which the government disapproves." David A. Strauss, Persuasion, Autonomy, and Freedom of Expression, 91 Colum. L. Rev. 334, 334 (1991).

Moreover, this justification for suppression of reduced-risk information would fail the third prong of the Central Hudson test because it would require the court "to engage in the sort of 'speculation or conjecture' that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the [government's] asserted interest." 44 Liquormart, 517 U.S. at 507. For example, in Rubin v. Coors Brewing Co., 514 U.S. 476 (1995), the Court concluded that the government's prohibition on displaying alcohol content on beer labels failed the third prong of Central Hudson

because it would not sufficiently advance the government's interests in preventing "strength wars" in the marketing of alcoholic beverages. The Court reasoned that the government's burden "is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Id. at 487(quoting Edenfield v. Fane, 507 U.S. 761, 770-771 (1993)).[2]

It is far from clear that suppressing reduced-risk information would "in fact alleviate" the perceived harms that might arise from the introduction of reduced-risk products. Any information suppressed by the government likely would find its way to consumers through other channels, though almost certainly in a less accurate form that has not been subject to scientific verification. As the IOM noted in its recent report on reduced-risk tobacco products, "marketplace forces already at work have put this issue on the public policy agenda" and consumers will seek out reduced-risk products "with or without scientific guidance." IOM Report at 201, 202. Moreover, as discussed below, any advance in the public health that purportedly results from the suppression of reduced-risk information would be undermined by the adverse effects of such suppression on individuals who would have used less risky tobacco products had the suppressed information been available to them.

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[2] When viewed from a more "utilitarian" perspective, these individuals are not benefited at all by the suppression of information. From this perspective, adults are better off if they are left free to make their own decisions based on full information. As University of Chicago Law School Professor Cass Sunstein puts it, "people should be allowed to select their preferred mixes of risk, employment, salary, medical care, and so forth." Cass R. Sunstein, Informing America: Risk, Disclosure, and the First Amendment, 20 Fla. St. U. L. Rev. 653, 659 (1993); see also Martin H. Redish, Tobacco Advertising and the First Amendment, 81 Iowa L. Rev. 589, 592 (1996) ("The asserted justifications for such regulation of the truthful promotion of a lawful product derive exclusively from a premise of governmental paternalism that is fundamentally

2. Real Harms Would Be Imposed by the Suppression of Information

Though the benefits to be derived from the suppression of reduced-risk or reduced-exposure information are speculative, it is clear that a separate group of individuals would be harmed by the suppression of such information. This group consists both of smokers who would have switched to reduced-risk products instead of continuing to use conventional tobacco products, and nonsmokers who would have begun using reduced-risk or reduced-exposure products instead of conventional tobacco products if they had been provided with information about them. Regardless of one's philosophical bent, everyone should agree that this group, which ends up taking on more risks solely because of the suppression of information, is substantially harmed by that suppression.

It is neither sound public policy nor constitutionally permissible for the government knowingly to harm a certain group of individuals by suppressing information for the presumed benefit of others. The Supreme Court held in the recent Western States decision that such a suppression of commercial speech cannot be reconciled with the First Amendment. Western States, 122 S.Ct. at 1508-09. In this decision, the Court invalidated provisions of the Food and Drug Modernization Act ("FDAMA") that prohibited advertising of "compounded drugs,"[3] which the government argued were necessary to ensure that drug compounding was not used to circumvent the new drug approval requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Id. at 1504-06.

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inconsistent with both the purposes served by free speech and the democratic system of which free speech is a central element.")

[3] Drug compounding, a "traditional component of the practice of pharmacy," is a process by which a pharmacist or doctor combines or alters drug ingredients to create a medication typically not commercially available and which is tailored to the needs of a particular individual, e.g., an individual that is allergic to an ingredient in a mass-produced product. Id. at 1500.

The Supreme Court found that the prohibition on advertising of compounded drugs was impermissible, *inter alia*, because of "the amount of beneficial speech" that it prohibited without furthering the asserted governmental objective. Id. at 1508.[4] Specifically, the Court pointed out that the prohibition would prevent pharmacists with "no interest in mass-producing medications" in circumvention of FDCA from telling doctors about alternative drugs available through compounding that would be useful in treating patients with special medical needs. Id. at 1508-09. The fact that such "useful speech" would be suppressed even though doing so would not "directly further" the government's asserted objective was "enough to convince" the Court that the challenged provisions were unconstitutional. Id. at 1509.

Thus, the suppression of reduced-risk information would be unconstitutional because it would result in real harm for certain groups of people without furthering a substantial governmental interest. The suppression of reduced-risk claims clearly would redound to the detriment of certain individuals -- i.e., those who, had they been exposed to the claims, would have switched to reduced-risk products from more risky conventional tobacco products. Moreover, the only motivation for suppressing truthful and non-misleading reduced-risk information would be the government's desire to prevent people from making choices based on the information that the government disfavors. Yet, as discussed above, the Constitution does not recognize such a motivation as a legitimate basis for restricting commercial speech. Under these circumstances, not only would the government impermissibly be saying that it knows what is best for certain of its citizens, but in doing so, it would affirmatively harm other citizens.

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[4] In response to the Western States decision, FDA issued a Federal Register notice seeking comments to "ensure that its regulations, guidances, policies, and practices continue to comply with the governing First

The government's decision to suppress reduced-risk information also has severe consequences for the individual and, indeed, for our system of government as a whole:

> [T]he fundamental premise of the First Amendment—indeed, of the very democratic system of which the First Amendment is such an important part—is that citizens must be trusted to make their own lawful choices on the basis of a free and open competition of ideas, opinions, and information. If government is permitted paternalistically to shield its citizens from such open debate as a means of controlling their behavioral choices, it will have simultaneously affronted individual dignity and stunted the individual's personal and intellectual growth, a developmental process that lies at the heart of the free speech right. It will simultaneously have contributed to an intellectual atrophy of the citizen that ultimately will undermine her effective participation in the democratic system.

Redish, Tobacco Advertising and the First Amendment, supra, at 636.

B. More Targeted Approaches Are Available to Address Public Health Concerns About Innovative Tobacco Products

Far more targeted approaches are available for the government to address concerns about the impact that reduced-risk and reduced-exposure tobacco products might have on the rates of smoking cessation and initiation. As a first step, the FDA would determine whether a product, as a matter of science, presents, or is likely to present, consumers with significantly reduced risks, or reduced exposure to toxic substances, compared with other tobacco products. Once the FDA has made this determination, it could ensure that this information is presented to consumers in a manner that is truthful and not misleading. Indeed, authority to prevent false and misleading product information is a standard FDA regulatory tool that currently applies to all product labeling and promotional materials regulated under FDCA, and that would specifically be

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Amendment case law." 67 Fed. Reg. 34,942 (May 16, 2002).

extended to tobacco products under S. 2626. In addition, other public health tools to encourage tobacco cessation and prevention are available and currently in use.

1. The Legislation Fails to Direct the FDA to Consider Appropriate Use of Disclaimers to Address Public Health Concerns

The Supreme Court held in Western States that "if the [g]overnment can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the [g]overnment must do so." Western States, 122 S.Ct. at 1506-07 (holding that the government failed to demonstrate that preserving the integrity of the FDCA drug approval process could not be achieved through means that imposed a lesser burden on speech than the FDAMA prohibition on advertising compounded drugs). Consequently, the advertising prohibition challenged in that case failed to satisfy the fourth prong of the Central Hudson test requiring that the restrictions not be more extensive than is necessary to serve the governmental interest. Id. See also Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) (there cannot be "an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive"); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d at 73 (FDA restrictions on particular forms of manufacturer promotion of off-label uses for FDA-approved drugs were considerably more extensive than necessary, and "[t]he most obvious alternative is full, complete, and unambiguous disclosure by the manufacturer").

In Western States, the Supreme Court identified the use of so-called "disclaimers" as an alternative way to ensure that consumers are not misled by advertisements. Western States, 122 S.Ct. at 1508 (a governmental interest in preventing misleading advertising could be achieved by "the far less restrictive alternative" of requiring compounded drugs to bear warnings stating that the drugs are not FDA-approved and that

their risks are unknown). The D.C. Circuit made the same conclusion in Pearson, stating that "we are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness . . .". Pearson, 164 F.3d at 659-660; see also In re R.M.J., 455 U.S. 191, 203 (1982) ("[T]he remedy in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation."). Furthermore, this principle is "consistent with a well-established body of law that points to First Amendment limits on federal agencies' restrictions on commercial speech where less restrictive alternatives are available." Steven B. Steinborn & Kyra A. Todd, The End of Paternalism: A New Approach to Food Labeling, 54 Food & Drug L.J. 401, 402 (1999). "Pearson stands as [a] reminder that regulatory agencies in general, and the FDA in particular, must adopt a regulatory approach that recognizes the consumer's right to receive pertinent information." Id. at 413-414.

Indeed, the Federal Trade Commission has long supported the position that disclaimers must be considered as an alternative when determining whether health claims about a product are misleading. See Nat'l Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977); Margaret Gilhooley, Constitutionalizing Food and Drug Law, 74 Tul. L. Rev. 815, 827 (2000); see also FTC Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388, 28,393 (1994) (noting that the "significant scientific agreement" standard in the Nutrition Labeling and Education Act of 1990 (NLEA) is the appropriate standard to determine if health claims are misleading only in situations where the claims are *unqualified*).

Providing consumers with additional information, such as through the use of disclaimers, is thus a more tailored means to address the impact that reduced-risk and reduced-exposure tobacco products might have on smoking cessation and initiation. "Any 'interest' in restricting the flow of accurate information because of the perceived danger of that knowledge is anathema to the First Amendment; *more speech and a better informed citizenry are among the central goals of the Free Speech Clause.*" Rubin, 514 U.S. at 497 (Stevens, J., concurring) (emphasis added). The FDA could require, for example, that every tobacco product designated as presenting a reduced-risk or reduced-exposure include labeling that reminds consumers that no tobacco product is safe and that the best option is to quit or not to start in the first place.

2. Other Public Health Tools are Available to Address Concerns Related to Smoking Cessation and Prevention

Of course, an FDA-imposed restriction on the communication of reduced-risk information is not the only policy tool available to address concerns related to tobacco use. As the IOM noted, the regulatory system it proposed should not be viewed in isolation, but rather "as an essential component of a package of public policy initiatives (including research, education and surveillance) that this committee believes is necessary to realize whatever benefit tobacco or pharmaceutical product innovation can offer in reducing the nation's burden of tobacco-related illness and death." IOM Report at 229. "Harm reduction [should be] implemented as a component of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment." Id.

In this regard, Congress appropriated a little over $100 million to the Centers for Disease Control for its tobacco control efforts in FY 2002. Indeed, the government

would have the burden of demonstrating that programs such as these could not adequately address the public health concerns raised by reduced-risk products, which would obviate the need to suppress reduced-risk information. "If the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort." Western States, 122 S.Ct. at 1507.[5]

[5] The Supreme Court ruled in Western States that the government must consider non-speech related alternatives before resorting to restrictions on commercial speech. In the decision, the Court identified several non-speech alternatives to FDAMA's compounded drug advertising prohibition that might be effective in achieving the government's interest of ensuring the integrity of FDCA's drug approval process. Id. at 1506. These were (1) banning the use of commercial scale manufacturing or testing equipment for compounding drug products; (2) prohibiting pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received; (3) prohibiting pharmacists from offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale; (4) limiting the amount of compounded drugs that a pharmacist may sell out of State or sell or make in a given period of time; or (5) relying on the non-speech related provisions of FDAMA, which include requiring that compounding only be conducted in response to a prescription or a history of receiving a prescription, and limiting the percentage of a pharmacy's total sales that out-of-state sales of compounded drugs may represent. Id. at 1506. The government's failure to explain why these alternatives would not be adequate led the Court to conclude that FDAMA's advertising prohibition was more extensive than necessary. Id. at 1506-07.

III. CONCLUSION

Based on these precedents and the IOM's recommendations, S. 2626 should ensure that adult consumers are provided with truthful and non-misleading information about these products. An outright ban on truthful and non-misleading speech regarding reduced-risk products would be inappropriate and unconstitutional. Instead, the FDA should be empowered to assess and approve reduced-risk and reduced-exposure products based on its findings regarding the genuine scientific merits of the claims, and then ensure that consumers are not misled about the risks associated with those products. Additional public health programs should continue to encourage smoking cessation and prevention.